

Package leaflet: Information for the user

Sodium oxybate 500 mg/ml oral solution

Sodium oxybate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Sodium oxybate is and what it is used for
2. What you need to know before you take Sodium oxybate
3. How to take Sodium oxybate
4. Possible side effects
5. How to store Sodium oxybate
6. Contents of the pack and other information

1. What Sodium oxybate is and what it is used for

Sodium oxybate contains the active substance sodium oxybate. This medicine works by consolidating night-time sleep, though its exact mechanism of action is unknown.

This medicine is used to treat narcolepsy with cataplexy in adults.

Narcolepsy is a sleep disorder that may include attacks of sleep during normal waking hours, as well as cataplexy, sleep paralysis, hallucinations and poor sleep. Cataplexy is the onset of sudden muscle weakness or paralysis without losing consciousness, in response to a sudden emotional reaction such as anger, fear, joy, laughter or surprise.

2. What you need to know before you take Sodium oxybate

Do not take Sodium oxybate

If you are allergic to sodium oxybate or any of the other ingredients of this medicine (listed in section 6);

- if you have succinic semialdehyde dehydrogenase deficiency (a rare metabolic disorder);
- if you suffer from major depression;
- if you are being treated with opioid or barbiturate medicines.

Warnings and precautions

Talk to your doctor or pharmacist before taking Sodium oxybate:

- if you have breathing or lung problems (and especially if you are obese), because this medicine has the potential to cause difficulty in breathing;
- if you have or have previously had depressive illness;
- if you have heart failure, hypertension (high blood pressure), liver or kidney problems as your dose may need to be adjusted;
- if you have previously abused drugs;
- if you suffer from epilepsy as the use of sodium oxybate is not recommended in this condition;
- if you have porphyria (an uncommon metabolic disorder).

If any of these apply to you, tell your doctor before you take Sodium oxybate.

While you are taking this medicine, if you experience bed wetting and incontinence (both urine and faeces), confusion, hallucinations, episodes of sleepwalking or abnormal thinking you should tell your doctor straight away. Whilst these effects are uncommon, if they do occur they are usually mild-to-moderate in nature.

If you are elderly, your doctor will monitor your condition carefully to check whether this medicine is having the desired effects.

Sodium oxybate has a well-known abuse potential. Cases of dependency have occurred after the illicit use of sodium oxybate. Your doctor will ask if you have ever abused any drugs before you start taking and whilst you are using this medicine.

Children and adolescents

Do not give this medicine to children and adolescents.

Other medicines and Sodium oxybate

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular Sodium oxybate **should not** be taken together with sleep inducing medicines and medicines that reduce central nervous system activity (the central nervous system is the part of the body related to the brain and spinal cord).

Also tell your doctor or pharmacist if you are taking any of the following types of medicines:

- medicines that increase central nervous system activity and antidepressants;
- medicines that may be processed in a similar way by the body (e.g., valproate, phenytoin or ethosuximide which are used for the treatment of fits);
- topiramate (used for treatment of epilepsy);

If you are taking valproate, your daily dose of Sodium oxybate will need to be adjusted (see section 3) as it may lead to interactions.

Sodium oxybate with food and alcohol

You must not drink alcohol while taking this medicine, as its effects can be increased.

Food decreases the amount of sodium oxybate that is absorbed by your body (see section 3).

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

There have been very few women who have taken sodium oxybate sometime during their pregnancy and a few of them had spontaneous abortions. The risk of taking sodium oxybate during pregnancy is unknown, and, therefore, the use of this medicine in pregnant women or women trying to become pregnant is not recommended.

Patients taking sodium oxybate should not breast-feed since it is known that sodium oxybate passes into breast milk. Changes in sleep patterns have been observed in breastfed infants from exposed mothers.

Driving and using machines

Sodium oxybate affects your ability to drive or operate tools or machines. Do not drive a car, operate machinery, or perform any activity that is dangerous or that requires mental alertness for at least 6 hours after taking this medicine. When you first start taking sodium oxybate, until you know

whether it makes you sleepy the next day, use extreme care while driving a car, operating machinery or doing anything else that could be dangerous or needs you to be fully mentally alert.

Sodium oxybate contains sodium

This medicine contains 0.41 g sodium (main component of cooking/table salt) in each 2.25 g dose. This is equivalent to 20 % of the recommended maximum daily dietary intake of sodium for an adult. Talk to your doctor or pharmacist if you need Sodium oxybate on a daily basis for a prolonged period of time, especially if you have been advised to follow a low salt (sodium) diet.

3. How to take Sodium oxybate

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended starting dose is 4.5 g/day, given as two equally divided doses of 2.25 g/dose. Your doctor may gradually increase your dose up to a maximum of 9 g/day given as two equally divided doses of 4.5 g/dose.

Take Sodium oxybate orally two times each night. Take the first dose upon getting into bed and the second dose 2.5 to 4 hours later. You may need to set an alarm clock to make sure you wake up to take the second dose. Food decreases the amount of sodium oxybate that is absorbed by your body. Therefore, it is best to take this medicine at set times 2 to 3 hours after a meal. Prepare both doses before bedtime. Take doses within 24 hours after preparation.

If you are taking valproate together with Sodium oxybate, the dose of sodium oxybate will be adapted by your doctor. The recommended starting dose for sodium oxybate, when used together with valproate, is 3.6 g/day, given as two equally divided doses of 1.8 g. Take the first dose upon getting into bed and the second dose 2.5 to 4 hours later.

If you have kidney problems, you should consider a dietary recommendation to reduce sodium intake.

If you have liver problems, the starting dose should be halved. Your doctor may gradually increase your dose.

Instructions on how to dilute Sodium oxybate

The following instructions explain how to prepare this medicine for use. Please read the instructions carefully and follow them step by step.

To help you, the Sodium oxybate carton contains one bottle of medicine, a dosing pipette and two dosing cups with child resistant screw caps.

1. Remove the bottle cap by pushing down while turning the cap anticlockwise (to the left). After removing the cap, set the bottle upright on a table-top. While holding the bottle in its upright position, insert the press-in bottle adapter into the neck of the bottle. This needs only to be done the first time that the bottle is opened. The adapter can then be left in the bottle for all subsequent uses.
2. Next, insert the tip of the dosing pipette into the centre opening of the bottle and press down firmly (see Figure 1). Make sure that the dosing pipette is tightly fixed.

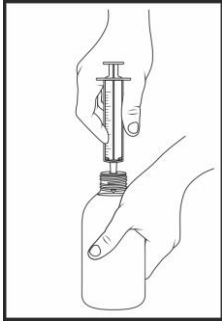


Figure 1

3. To fill pipette, turn the bottle upside down. Whilst holding the pipette in place, gently pull the plunger down drawing the medicine to the prescribed dose (see Figure 2).

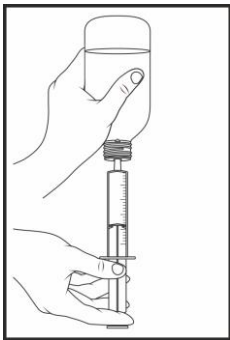


Figure 2

4. Turn the bottle the right way up. Remove the pipette from the centre opening of the bottle. Empty the medicine from the pipette into one of the dosing cups provided by pushing on the plunger (see Figure 3). Repeat this step for the second dosing cup. Then add about 60 ml of water to each dosing cup (60 ml is about 4 tablespoons).

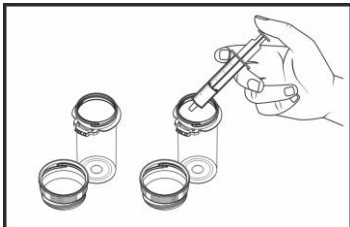


Figure 3

5. Place the caps provided on the dosing cups and turn each cap clockwise (to the right) until it clicks and locks into its child resistant position (see Figure 4). Rinse out the pipette with water.



Figure 4

6. Just before going to sleep, place your second dose near your bed. You may need to set an alarm so you wake up to take your second dose no earlier than 2.5 hours and no later than 4 hours after your first dose. Remove the cap from the first dosing cup by pressing down on the child resistant locking tab and turning the cap anticlockwise (to the left). Drink all of the first dose while sitting in bed, recap the cup, and then lie down right away.
7. When you wake up 2.5 to 4 hours later, remove the cap from the second dosing cup. While sitting in bed, drink all of the second dose right before lying down to continue sleeping. Recap the second cup.

Each subsequent time when preparing this medicine, follow steps 2 to 7.

Keep all the package until the end of treatment.

If you have the impression that the effect of Sodium oxybate is too strong or too weak, talk to your doctor or pharmacist.

If you take more Sodium oxybate than you should

Symptoms of sodium oxybate overdose may include agitation, confusion, impaired movement, impaired breathing, blurred vision, profuse sweating, headache, vomiting, decreased consciousness leading to coma and seizures, excessive thirst, muscle cramps and weakness. If you take more sodium oxybate than you were told to take, or take it by accident, get emergency medical help right away. You should take the labelled medicine bottle with you, even if it is empty.

If you forget to take Sodium oxybate

If you forget to take the first dose, take it as soon as you remember and then continue as before. If you miss the second dose, skip that dose and do not take this medicine again until the next night. Do not take a double dose to make up for a forgotten dose.

If you stop taking Sodium oxybate

You should continue to take this medicine for as long as instructed by your doctor. You may find that your cataplexy attacks return if your medicine is stopped and you may experience insomnia, headache, anxiety, dizziness, sleeping problems, sleepiness, hallucination and abnormal thinking.

If you stop taking Sodium oxybate for more than 14 consecutive days you should consult your doctor as you should restart taking this medicine at a reduced dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. These are usually mild to moderate. If you experience any of these, tell your doctor straight away.

Very common (may affect more than 1 in 10 people)

Nausea, dizziness, headache.

Common (may affect up to 1 in 10 people)

Sleeping problems including insomnia, blurred vision, feeling the heart beat, vomiting, stomach pains, diarrhoea, anorexia, decreased appetite, weight loss, weakness, abnormal dreams, tiredness, feeling drunk, sleep paralysis, sleepiness, trembling, confusion/ disorientation, nightmares, sleep walking, bed wetting, sweating, depression, muscle cramps, swelling, fall, joint pain, back pain, excessive daytime sleepiness, balance disorder, disturbance in attention, decreased sensitivity particularly to touch, abnormal touch sensation, feeling of “pins and needles” (part of the body (typically a foot or hand) begins to tingle and becomes numb, or “falls asleep”, sedation, abnormal taste, anxiety, difficulty in

falling asleep in the middle of the night, nervousness, feeling of “spinning” (vertigo), urinary incontinence, shortness of breath, snoring, congestion of the nose, rash, inflammation of the sinuses, inflammation of nose and throat, increased blood pressure.

Uncommon (may affect up to 1 in 100 people)

Psychosis (a mental disorder that may involve hallucinations, incoherent speech, or disorganized and agitated behaviour), paranoia, abnormal thinking, hallucination, agitation, suicide attempt, difficulty in falling asleep, restless legs, forgetfulness, myoclonus (involuntary contractions of muscles), involuntary passage of faeces, hypersensitivity.

Not known (cannot be estimated from the available data)

Convulsion, decreased breathing depth or rate, hives, suicidal thoughts, short cessation of breathing during sleep, euphoric mood, dry mouth, swelling face (angioedema), dehydration, panic attack, mania/bipolar disorder, delusion, bruxism (teeth grinding and jaw clenching), pollakiuria/micturition urgency (increased need to urinate), nocturia (excessive urination at night), tinnitus (noise in the ears such as ringing or buzzing), sleep-related eating disorder, loss of consciousness, increased appetite, irritability, aggression, dyskinesia (e.g. abnormal, uncontrolled movements of the limbs) and thoughts of committing violent acts (including harming others), dandruff and increased sexual desire.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sodium oxybate

This medicinal product does not require any special storage conditions.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.

After dilution in the dosing cups, the preparation should be used within 24 hours.

Once you open a bottle of Sodium oxybate, any contents that you have not used with 90 days of opening should be disposed of.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Sodium oxybate contains

- The active substance is sodium oxybate. Each ml of solution contains 500 mg of sodium oxybate.
- The other ingredients are malic acid (for pH adjustment), sodium hydroxide (for pH adjustment), purified water.

What Sodium oxybate looks like and contents of the pack

Sodium oxybate is a clear to slightly opalescent colourless to yellowish solution.

180 ml of solution in a 200 ml amber plastic bottle which is closed with a child resistant tamper evident cap. Each carton contains one bottle, a press-in bottle adapter, a graduated dosing pipette (graduated for dosing from 1.5 g to 4.5 g) and two dosing cups with child resistant screw caps.

Marketing Authorisation Holder and Manufacturer

AS KALCEKS

Krustpils iela 71E, Rīga, LV-1057, Latvia

Tel.: +371 67083320

E-mail: kalceks@kalceks.lv

This medicine is authorised in the Member States of the European Economic Area under the following names:

Estonia	Sodium oxybate Kalceks
Austria	Natriumoxybat Kalceks 500 mg/ml Lösung zum Einnehmen
Belgium	Oxybate Kalceks 500 mg/ml, drank Oxybate Kalceks 500 mg/ml, solution buvable Oxybate Kalceks 500 mg/ml, Lösung zum Einnehmen
Czech Republic	Sodium oxybate Kalceks
Denmark	Natriumoxybat Kalceks
Germany	Natriumoxybat Ethypharm 500 mg/ml Lösung zum Einnehmen
Spain	Oxibato de sodio Kalceks 500 mg/ml solución oral EFG
Finland	Natriumoksibaatti Kalceks
France	OXYBATE DE SODIUM KALCEKS 500 mg/mL, solution buvable
Ireland	Sodium oxybate 500 mg/ml oral solution
Italy	Sodio oxibato Kalceks
Lithuania	Sodium oxybate Kalceks 500 mg/ml geriamasis tirpalas
Latvia	Nartex 500 mg/ml šķīdums iekšējīgai lietošanai
The Netherlands	Natriumoxybaat Kalceks 500 mg/ml drank
Norway	Natriumoksybat Kalceks
Sweden	Natriumoxibat Kalceks
Slovenia	Natrijev oksibat Kalceks 500 mg/ml peroralna raztopina
Slovak Republic	Sodium oxybate Kalceks 500 mg/ml perorálny roztok

This leaflet was last revised in 02/2024